UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

FRESENIUS KABI USA, LLC, *Plaintiff*, v. AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, and AMNEAL EU, LIMITED, *Defendants*.	Civil Action No. _____

COMPLAINT

Fresenius Kabi USA, LLC ("Fresenius" or "Plaintiff") brings this action for patent infringement against Defendants Amneal Pharmaceuticals LLC ("Amneal Pharma"), Amneal Pharmaceuticals of New York, LLC ("Amneal NY"), and Amneal EU, Limited ("Amneal EU") (collectively, "Amneal" or "Defendants").

1. This is an action by Fresenius against Defendants for infringement of United States Patent No. 8,476,010 ("the '010 patent"). This action arises out of Defendants' filing of an Abbreviated New Drug Application ("ANDA") seeking approval by the United States Food and Drug Administration ("FDA") to sell a generic version of Diprivan®, an innovative intravenously administered sedative and anesthetic, prior to the expiration of the '010 patent.

THE PARTIES

Plaintiff

2. Fresenius is a Delaware limited liability company with its principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047. Fresenius was formerly known as APP Pharmaceuticals, LLC.

Defendants

3. Upon information and belief, Defendant Amneal Pharma is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at 400 Crossing Boulevard, 3rd Floor, Bridgewater, NJ 08807.

4. Upon information and belief, Defendant Amneal NY is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Crossing Boulevard, 3rd Floor, Bridgewater, NJ 08807. Upon information and belief, Amneal NY is a wholly owned subsidiary of Amneal Pharma. Upon information and belief, Amneal NY is the U.S. agent for Amneal EU.

5. Upon information and belief, Defendant Amneal EU is a company organized and existing under the laws of Ireland, having a place of business at Cahir Road, Cashel, Co. Tipperary, Ireland E25 XD5l. Upon information and belief, Amneal EU is an indirect wholly owned subsidiary of Amneal Pharma.

JURISDICTION AND VENUE

Subject Matter Jurisdiction

6. This action for patent infringement arises under 35 U.S.C. § 271.

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

Personal Jurisdiction

8. Upon information and belief, this Court has personal jurisdiction over Defendants because, *inter alia,* they have maintained continuous and systematic contacts with the State of New Jersey.

9. Upon information and belief, this Court also has personal jurisdiction over Defendants because*, inter alia,* they have committed, or aided, abetted, contributed to, or

participated in the commission of, tortious conduct, which will lead to foreseeable harm and injury to Fresenius in the State of New Jersey, and by doing so, Defendants have purposefully directed their activities at the residents of this forum.

10. Upon information and belief, this Court has personal jurisdiction over Defendant Amneal Pharma because it has its principal place of business in New Jersey.

11. Upon information and belief, this Court has personal jurisdiction over Defendant Amneal NY because it has its principal place of business in New Jersey.

12. Upon information and belief, this Court has personal jurisdiction over Defendant Amneal EU because its U.S. agent, Amneal NY, has its principal place of business in New Jersey.

13. Upon information and belief, Defendants have previously availed themselves of this Judicial District by not contesting personal jurisdiction in at least the following actions: *Cubist Pharms. LLC v. Amneal Pharms. LLC et al.*, Civil Action No. 3:19-cv-15439 (D.N.J. filed July 16, 2019); and *TherapeuticsMD, Inc. v. Amneal Pharms., Inc. et al.*, Civil Action No. 3:20-cv-05256-FLW-TJB (D.N.J. filed Apr. 29, 2020).

14. Upon information and belief, Defendants have engaged in continuous and systematic contacts with the State of New Jersey and/or purposefully have availed themselves of this forum by, *inter alia*, individually and/or in concert, making, marketing, shipping, using, offering to sell or selling Defendants' pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities.

15. Upon information and belief, Defendants have engaged in and maintained systematic and continuous business contacts within the State of New Jersey, and have purposefully availed themselves of the benefits and protections of the laws of the State of New Jersey, rendering them at home in the State of New Jersey.

16. Upon information and belief, Defendants operate as a single vertically-integrated business with respect to the regulatory approval, manufacturing, marketing, sale and distribution of pharmaceutical products throughout the United States, including in this Judicial District.

17. Upon information and belief, Defendants, individually and/or in concert, have committed, or aided, abetted, contributed to and/or participated in the commission of the tortious action of patent infringement that has led to foreseeable harm and injury to Fresenius, which sells Diprivan® for use throughout the United States, including the State of New Jersey.

18. Upon information and belief, Defendants have applied for FDA approval to market and sell a generic version of Diprivan® throughout the United States, including the State of New Jersey.

19. Defendants' submission of their ANDA to FDA evinces their intent to subject themselves to the jurisdiction of the courts where the drug that is the subject of the ANDA will be sold, including in the State of New Jersey.

20. Defendants sent a letter, dated June 28, 2023 (the "Notice Letter"), to Fresenius stating that Defendants had filed ANDA No. 217525 seeking FDA approval to market generic Diprivan® products ("Defendants' generic Diprivan® products") prior to the expiration of the '010 patent. The Notice Letter was sent from the State of New Jersey by Bryan Sommese, Esq., Senior Patent Litigation Counsel IP, for Amneal Pharma in Bridgewater, New Jersey, on behalf of Amneal NY and Amneal EU.

21. Upon information and belief, Defendants acted in concert to prepare and submit ANDA No. 217525.

22. Upon information and belief, Defendants, individually and/or in concert, will market, sell and offer for sale Defendants' generic Diprivan® products in the State of New Jersey following FDA approval of those products.

23. Upon information and belief, as a result of Defendants' marketing, selling, or offering for sale of Defendants' generic Diprivan® products in the State of New Jersey, Fresenius will lose sales of Diprivan® and be injured in the State of New Jersey.

24. This Court's exercise of jurisdiction over Defendants is fair and reasonable. Defendants are not burdened by litigating this suit in the State of New Jersey. The State of New Jersey has an interest in providing a forum to resolve Hatch-Waxman litigation, including in this case, because this case involves products that will be sold in the State of New Jersey by New Jersey-based companies and injury to Fresenius in the State of New Jersey. This Court's exercise of jurisdiction serves the interests of the judicial system in efficient resolution of Hatch-Waxman litigation.

25. Upon information and belief, this Court has personal jurisdiction over Defendants for the reasons stated herein, including, *inter alia,* Defendants' activities in the forum, activities directed at the forum, and significant contacts with the forum, all of which render Defendants at home in the forum. Personal jurisdiction is proper at least under *Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755 (Fed. Cir. 2016).

26. In the alternative, Defendant Amneal EU is subject to personal jurisdiction in this forum under Federal Rule of Civil Procedure 4(k)(2).

Venue

27. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and 1400(b). *In re HTC Corp.*, 889 F.3d 1349, 1354 (Fed. Cir. 2018).

28. Upon information and belief, Defendants have a regular and established place of

business in this Judicial District and have committed and/or will commit acts of infringement in this Judicial District.

29. Upon information and belief, Defendants have not contested venue in this Judicial District in at least the following actions: *Cubist Pharms. LLC v. Amneal Pharms. LLC et al.*, Civil Action No. 3:19-cv-15439 (D.N.J. filed July 16, 2019); and *TherapeuticsMD, Inc. v. Amneal Pharms., Inc. et al.*, Civil Action No. 3:20-cv-05256-FLW-TJB (D.N.J. filed Apr. 29, 2020).

30. Upon information and belief, Defendant Amneal Pharma has a regular and established place of business in this Judicial District at least because it: (1) has a principal place of business in the State of New Jersey; (2) has acted in concert with Amneal NY and Amneal EU to seek approval from FDA to market and sell Defendants' generic Diprivan® products in this Judicial District; (3) has engaged in regular and established business contacts with the State of New Jersey by, *inter alia*, contracting and engaging in related commercial activities related to the marketing, making, shipping, using, offering to sell or selling Defendants' products in this Judicial District, and deriving substantial revenue from such activities; and (4) has made agreements with retailers, wholesalers or distributors providing for the distribution of Defendants' products in the State of New Jersey.

31. Upon information and belief, Defendant Amneal NY has a regular and established place of business in this Judicial District at least because it: (1) has a principal place of business in New Jersey; (2) has acted in concert with Amneal Pharma and Amneal EU to seek approval from FDA to market and sell Defendants' generic Diprivan® products in this Judicial District; (3) has engaged in regular and established business contacts with the State of New Jersey by, *inter alia*, contracting and engaging in related commercial activities related to the marketing, making, shipping, using, offering to sell or selling Defendants' products in this Judicial District, and

deriving substantial revenue from such activities; and (4) has made agreements with retailers, wholesalers or distributors providing for the distribution of Defendants' products in the State of New Jersey.

32. Upon information and belief, Defendant Amneal EU has a regular and established place of business in this Judicial District at least because it: (1) conducts business, individually and/or in concert with its U.S. agent, which is located in the State of New Jersey, in this Judicial District; and (2) has engaged in regular and established business contacts with the State of New Jersey by, *inter alia*, marketing, making, shipping, using, offering to sell or selling Defendants' products in this Judicial District, and deriving substantial revenue from such activities.

33. Venue is also proper in this Judicial District for Amneal EU at least because, *inter alia*, Amneal EU is a foreign corporation organized and existing under the laws of Ireland and may be sued in any judicial district in which it is subject to personal jurisdiction, including in the State of New Jersey.

BACKGROUND

The Patent-in-Suit: United States Patent No. 8,476,010

34. The '010 patent, entitled "Propofol Formulations with Non-Reactive Container Closures," was duly and lawfully issued on July 2, 2013, to inventors Neil P. Desai, Andrew Yang, and Sherry Xiaopei Ci. The named inventors assigned the '010 patent to APP Pharmaceuticals, LLC, which later changed its name to Fresenius Kabi USA, LLC. Accordingly, Fresenius is the owner of all rights, title and interest in the '010 patent. The '010 patent will expire, with a period of pediatric exclusivity, on June 1, 2025. A true and accurate copy of the '010 patent is attached hereto as Exhibit A.

35. The '010 patent is listed in FDA's publication entitled, "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly referred to as "The Orange Book," with respect to Diprivan®.

36. On or about January 16, 2020, after the conclusion of *inter partes* review (and the appeal therefrom), the United States Patent and Trademark Office cancelled claims 1, 13-15, 17, 18, 20 and 24-28 of the '010 patent. Fresenius is not asserting any of claims 1, 13-15, 17, 18, 20 and 24-28 of the '010 patent in this action. The remaining claims of the '010 patent are, and remain, valid and enforceable.

The Diprivan® Drug Product

37. Fresenius currently sells, promotes, distributes and markets Diprivan® (propofol) injectable emulsion in the United States.

38. Diprivan® is indicated, generally speaking, for the induction and maintenance of general anesthesia and sedation in certain patient populations.

39. Fresenius holds an approved New Drug Application ("NDA") No. 19627, under Section 505(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(a), for and in connection with the Diprivan® (propofol) injectable emulsion product containing 10 mg propofol per 1 mL of emulsion.

Defendants' ANDA

40. Defendants filed with the FDA an ANDA, under 21 U.S.C. § 355(j) ("Defendants' ANDA"), seeking approval to manufacture, use, offer for sale, sell in and import into the United States Defendants' generic Diprivan® products (Propofol Injectable Emulsion USP, 10 mg/mL, in 20 mL, 50 mL and 100 mL single-dose vials), prior to the expiration of the '010 patent.

41. The FDA assigned Defendants' ANDA the number 217525.

42. Defendants filed with FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the claims of the '010 patent are invalid, unenforceable and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of Defendants' generic Diprivan® products ("Defendants' Paragraph IV Certification"). Defendants notified Fresenius of Defendants' Paragraph IV Certification in their Notice Letter, dated June 28, 2023, sent by United Parcel Service.

43. This action is being commenced within forty-five (45) days of Fresenius' receipt of Defendants' Notice Letter.

COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 8,476,010 BY DEFENDANTS

44. The allegations of paragraphs 1-43 are realleged and incorporated herein by reference.

45. Defendants have infringed the '010 patent by submitting and maintaining Defendants' ANDA to and before FDA seeking approval to market Defendants' generic Diprivan® products before the expiration of the '010 patent.

46. The use of Defendants' generic Diprivan® products is covered by one or more claims of the '010 patent literally and/or under the doctrine of equivalents.

47. Upon information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Defendants' generic Diprivan® products would infringe one or more claims of the '010 patent, for example, at least claim 21 of the '010 patent.

48. Claim 21, which depends directly from claim 1, claims and is directed to: a sterile pharmaceutical composition of propofol in a container, comprising: a container which includes a closure and a composition in the container, and the composition in the container comprising from 0.5% to 10% by weight propofol and from about 0 to about 10% by weight solvent for propofol,

where when the composition in the container sealed with the closure is agitated at a frequency of 300-400 cycles/minute for 16 hours at room temperature, the composition maintains a propofol concentration (w/v) measured by HPLC that is at least 93% of the starting concentration (w/v) of the propofol; where the closure is selected from the group consisting of siliconized bromobutyl rubber, metal, and siliconized chlorobutyl rubber; and wherein the closure also comprises metal.

49. Upon information and belief, Defendants' generic Diprivan® products comprise: a sterile pharmaceutical composition of propofol in a container; a container which includes a closure and a composition in the container; a composition in the container comprising from 0.5% to 10% by weight propofol and from about 0 to about 10% by weight solvent for propofol, where when the composition in the container sealed with the closure is agitated at a frequency of 300-400 cycles/minute for 16 hours at room temperature, the composition maintains a propofol concentration (w/v) measured by HPLC that is at least 93% of the starting concentration (w/v) of the propofol; a closure selected from the group consisting of siliconized bromobutyl rubber, metal, and siliconized chlorobutyl rubber; and wherein the closure also comprises metal.

50. Defendants' Notice Letter does not contest, or otherwise assert any grounds challenging, the validity or enforceability of claim 21 of the '010 patent.

51. Defendants were aware of the '010 patent prior to the submission of Defendants' ANDA and were further aware that filing Defendants' ANDA with Defendants' Paragraph IV Certification constituted an act of infringement of the '010 patent.

52. Upon information and belief, Defendants intend to engage, or direct or induce others to engage, in the manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Defendants' generic Diprivan® products immediately and imminently upon approval of Defendants' ANDA.

53. The foregoing actions by Defendants constitute and/or would constitute direct, induced and/or contributory infringement of the '010 patent.

54. Fresenius will be substantially and irreparably harmed by Defendants' infringing activities unless the Court enjoins those activities. Fresenius will have no adequate remedy at law if Defendants are not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of Defendants' generic Diprivan® products.

COUNT II FOR DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,476,010 BY DEFENDANTS

55. The allegations of paragraphs 1-54 are realleged and incorporated herein by reference.

56. Upon information and belief, Defendants plan to begin manufacturing, marketing, selling, offering to sell and/or importing Defendants' generic Diprivan® products soon after FDA approval of Defendants' ANDA.

57. Upon information and belief, such conduct will constitute direct or indirect infringement of one or more claims of the '010 patent under 35 U.S.C. § 271.

58. Defendants' infringing activity complained of herein is imminent and will begin following FDA approval of Defendants' ANDA.

59. As a result of the foregoing facts, there is a real, substantial and continuing justiciable controversy between Fresenius and Defendants as to liability for infringement of the '010 patent. Defendants' actions have created in Fresenius a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

60. Fresenius will be irreparably harmed if Defendants are not enjoined from infringing the '010 patent.

PRAYER FOR RELIEF

WHEREFORE, Fresenius respectfully requests the following relief:

a. A judgment that Defendants' submission of Defendants' ANDA No. 217525 infringes one or more claims of the '010 patent and that the making, using, offering to sell or selling in the United States, or importing into the United States of Defendants' generic Diprivan® products prior to the expiration of the '010 patent will infringe one or more claims of the '010 patent;

b. An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Defendants' ANDA No. 217525 seeking approval to manufacture, use, offer for sale, sell in and import into the United States Defendants' generic Diprivan® products or any product or compound the use of which infringes the '010 patent, shall be a date that is not earlier than the expiration of the '010 patent, including any period of pediatric exclusivity;

c. An Order permanently enjoining Defendants and all persons acting in concert with Defendants from commercially manufacturing, using, offering for sale, selling, marketing, distributing or importing Defendants' generic Diprivan® products, or any other product or compound the use of which infringes the '010 patent, or inducing or contributing to the infringement of the '010 patent, until after the expiration of the '010 patent;

d. An Order enjoining Defendants and all persons acting in concert with Defendants from seeking, obtaining or maintaining approval of Defendants' ANDA No. 217525 before the expiration of the '010 patent;

e. An award of Fresenius' damages or other monetary relief to compensate Fresenius if Defendants engage in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into, the United States of Defendants' generic

Diprivan® products, or any product or compound the use of which infringes the '010 patent, prior to the expiration of the '010 patent in accordance with 35 U.S.C. § 271(e)(4)(C);

f. An award of Plaintiff's reasonable costs and expenses in this action; and

g. An award of any further and additional relief to Plaintiff as this Court deems just and proper, including attorneys' fees under 35 U.S.C. § 285 if supported by the totality of the circumstances.

Dated: August 11, 2023

Respectfully submitted,

/s/ Eric I. Abraham
ERIC I. ABRAHAM

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